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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,885	07/30/2003	Karla Weaver	10142/01601	7939
30636 7590 11/17/2009 FAY KAPLUN & MARCIN, LLP 150 BROADWAY, SUITE 702 NEW YORK, NY 10038				
EXAMINER				
STIGELL, THEODORE J				
ART UNIT		PAPER NUMBER		
3763				
MAIL DATE		DELIVERY MODE		
11/17/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/630,885

Applicant(s)

WEAVER ET AL.

Examiner

THEODORE J. STIGELL

Art Unit

3763

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-26 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-19 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-19, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daly et al. (US 2004/0186444) in view of Twyman (2,755,060). Daly discloses a valve apparatus that (see at least Figure 2) that includes two lumens (212, 214) with two valves (220, 230) wherein the valves are biased in the closed configuration and configured to open at a predetermined pressure. Daly does not appear to disclose the inclusion of biasing members coupled to the valves in order to further bias the valves in the closed position. Twyman discloses a valve member (14) which includes a slit (16) that is biased in a closed configuration and further includes a biasing member (18) coupled to the valve member that further biases the slit in the

closed configuration. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Daly with the biasing member of Twyman in order to create a valve assembly that is firmly biased in the closed configuration in order to avoid problems such as leakage.

Claims 15-17 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (4,244,379) in view of Twyman (2,755,060). Smith discloses most of the limitations recited in the claims listed above but fails to explicitly teach a biasing element coupled to the flexible disk adjacent to the first slit to urge the moveable elements towards the closed position as is now recited. Twyman discloses a valve member (14) which includes a slit (16) that is biased in a closed configuration and further includes a biasing member (18) coupled to the valve member that biases the slit in the closed configuration. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Smith with the biasing member of Twyman in order to create a valve assembly that is firmly biased in the closed configuration in order to avoid problems such as leakage.

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (4,244,379) and Twyman (2,755,060) in further view of Jones (2,720,881). Smith and Twyman together disclose all of the limitations recited in claim 15. However, they do not disclose a pair of second perpendicular slits intersecting the first slit. Jones teaches such a configuration and teaches that this configuration is useful in pressure actuated valves. Therefore, it would have been obvious to one of ordinary skill in the art at the

time of the invention to modify the combination of Smith and Twyman with the valve configuration of Jones to make an improved pressure actuated valve.

Response to Arguments

Applicant's arguments filed 6/3/2009 have been fully considered but they are not persuasive.

Daly et al. (US 2004/0186444) and Twyman (2,755,060)

In response to the applicant's argument that Twyman fails to teach a biasing member that urges movable elements to a closed position but also permits fluid flow therepast upon application of a threshold pressure, the examiner respectfully disagrees. The examiner maintains that the biasing member will allow fluid flow upon some fluid pressure.

Smith (4,244,379) in view of Twyman (2,755,060)

In response to the applicant's argument that Smith fails to teach "a valve element including a flexible disk...that...when a pressure at least as great as the threshold value is applied to the flexible disk, the movable elements are moved to an open position" in combination with a *"dialysis connector comprising a valve housing having a first end connectable to a patient line and a second end mounted to a dialysis line; a flow passage of the housing being connected to the patient line and being operatively connectable to the dialysis line,"*, the examiner respectfully disagrees. The examiner maintains that the valve elements of Smith are capable of being moved open by fluid pressure and the device is capable of being attached to a patient line and a dialysis line.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **THEODORE J. STIGELL** whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763